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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,818

12/07/2004

Junzo Tanaka

043070

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38834

7590

04/17/2009

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP
1250 CONNECTICUT AVENUE, NW
SUITE 700
WASHINGTON, DC 20036

EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/516,818	Applicant(s) TANAKA ET AL.	
	Examiner David M. Naff	Art Unit 1657	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: None.
 Claim(s) objected to: _____.
 Claim(s) rejected: 9-11 and 14-17.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

/David M. Naff/
 Primary Examiner, Art Unit 1657

Continuation of 3. NOTE: New issues raised that would require further consideration and/or search by claim 9 reciting "increasing linear gradient" (line 7) and "the the" (line 11), and method claim 15 not having antecedent basis for "the second side" (line 5), and being an incomplete method for preparing the composite material of claim 9.

Continuation of 11. does NOT place the application in condition for allowance because: In response to the 35 USC 112, second paragraph rejection of claim 15, the amendment urges that claims reciting a complete process is not required. However, it is required that the claims be definite by particularly pointing out and distinctly claiming the subject matter that is the invention. A process claim drawn to producing a product, and which recites less than all process steps essential to produce the product does not particularly point out and distinctly claim the subject matter that is the invention, and is indefinite. The amendment points out that claim 15 has been amended to recite a step of providing a polymeric material. However, the amendment has not been entered. Even if entered, claim 15 does not recite a complete process for producing the composite of claim 9. Claim 15 does not require the polymeric material to have a first and second side, and alternatively soaking to form a gradient of calcium phosphate that varies in the biodegradable polymeric material from the first side to the second side of the biodegradable polymeric material with an increasing linear gradient. Claim 15 does not have antecedent basis for "the second side", and a second side cannot be present unless there is a first side. One side is not a second side.

In regard to the 35 USC 103 rejection, the amendment urges that soaking alternatively by references involves soaking the whole material. However, soaking only one side would have been obvious when hydroxyapatite is desired on only one side. When the material is porous such that calcium and phosphate ions can be absorbed, the soaking will inherently result in a gradient.

The amendment urges that the references do not disclose or suggest an embodiment where a gradient increases from one side to another. However, when the material is collagen disclosed by Akashi et al (col 4 line 15) or cross-linked collagen and glycosaminoglycan disclosed by Mattern et al or Yannas et al, the material is porous, and soaking will inherently result in calcium and phosphate ions being absorbed into the material and forming a gradient where the concentration of calcium phosphate is higher at the surface contacted with the calcium and phosphate ions and decreases towards to the other side. Taguchi et al (Biomaterials) disclose (page 3, 2nd complete paragraph) forming bone-like apatite on/in a three-dimensional hydrogel matrix by alternative soaking. This supports that calcium phosphate will be formed both at the surface and inside a porous matrix when subjected to the alternative soaking.

The amendment urges that amended claim 9 requires soaking the second side, and this results in the second side having a greater amount of calcium phosphate. However, when alternatively soaking one side, which is obvious as set forth above, the surface of this side can be considered a second side, and a greater amount of calcium phosphate will obviously be at this side since this side has the surface that is contacted with the alternative soaking solutions. When soaking the whole material as disclosed by Akashi et al and Taguchi et al, the surface of the whole material contacted with the alternative soaking solutions has the greater amount of calcium phosphate as when the second side is contacted with the alternative solutions in claim 9. An unexpected result is not seen from contacting one side of a material alternatively with calcium and phosphate solutions as claimed as compared to contacting a whole material alternatively with calcium and phosphate solutions as disclosed by Akashi et al and Taguchi et al. Alternative soaking of a whole material will result in a gradient from the surface to within the interior of the material when the material is porous. Both methods result in a hydroxyapatite composite that can be used as an implant, and soaking only one side has not been established to provide a composite having a different function.